UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

THE KINETIC CO., INC., on behalf of itself and all others similarly situated,	**CASE No.: 08-6062 (JRT/AJB)**
Plaintiff,	
v.	**DEFENDANT MEDTRONIC, INC.'S MEMORANDUM IN SUPPORT OF JUDGMENT ON THE PLEADINGS**
MEDTRONIC, INC.,	
Defendant.	

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Defendant Medtronic, Inc. (Medtronic) respectfully submits this memorandum of law in support of its motion for judgment on the pleadings, pursuant to Fed. R. Civ. P. 12(c), on all claims of plaintiff The Kinetic Company, Inc. (Kinetic).

INTRODUCTION

This is the second putative class action lawsuit Kinetic, a self-insured industrial knife company, has filed against Medtronic for its sale and distribution of certain allegedly defective implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy devices (CRT-D). While the basic factual allegations underlying the two lawsuits are essentially the same, the preemption legal landscape is not. Since Kinetic's original lawsuit, the Supreme Court, in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and the Eighth Circuit, in its recent decision *Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010), have made clear that Kinetic's claims are preempted by Section 360k(a) of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 360k(a).

On November 5, 2008, Kinetic, seeking to represent a putative class of third party payors, filed a Complaint bringing claims against Medtronic "for its sale and distribution of defective implantable cardi[overter] defibrillators ('ICD') and cardiac resynchronization therapy devices ('CRT-D'), and for its otherwise

wrongful marketing, promotion, advertising and sale of these devices." Kinetic's Complaint (Dkt. # 1-1) pleaded a host of state law causes of action, including claims for negligence, negligence per se, strict liability design and manufacturing defect, and strict liability failure to warn. Presumably recognizing that these negligence and strict liability claims were preempted, Kinetic filed an Amended Complaint on June 22, 2010 (Dkt. # 57), retaining only its causes of action from the original Complaint that Medtronic violated consumer protection statutes, breached express and implied warranties, and made material misrepresentations to Kinetic and the public.

Kinetic's Amended Complaint, however, suffers the same fatal defect as its original Complaint: All of Kinetic's claims are preempted by the MDA to the FDCA, as interpreted by the Supreme Court in *Riegel*, and by the Eighth Circuit in its recent decision *Bryant*, and, therefore, judgment for Medtronic is warranted.

Despite Kinetic's attempt to re-title its claims to avoid preemption, these claims attack medical devices whose design, construction, manufacturing methods, testing, and labeling were specifically approved by the Food and Drug Administration (FDA) pursuant to that agency's premarket approval (PMA) process. An FDA-approved Class III medical device, by definition, "support[s] or sustain[s] human life" or "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii). As the Supreme Court made clear in *Riegel*,

the decision to authorize the sale of novel Class III devices through the PMA process requires a "cost-benefit analysis"—a balancing of the potential public benefits of the device with its potential to cause harm. 552 U.S. at 325. *Riegel* further observed that juries are ill-equipped to perform this cost-benefit analysis because, *inter alia*, they "see[] only the cost[s]" of a device—that is, its potential to cause harm—and are "not concerned with its benefits; the patients who reaped those benefits are not represented in court." *Id.*

Because Congress found that it is in the public interest to encourage the development of these life-saving devices even though they may pose a risk of injury to some people, it placed exclusive responsibility for conducting the cost-benefit analyses for such novel premarket-approved devices in the hands of an expert federal agency, the FDA. Furthermore, to ensure that manufacturers would not be subjected to inconsistent or additional standards and to create a climate that encourages innovation and development of these devices, Congress explicitly prohibited any state-law claim that would impose a standard that is "different from, or in addition to" the standards imposed by the FDA. *Id.* at 321-28; *Bryant*, 623 F.3d at 1204-05.

In the two years since *Riegel* was decided, courts across the country have consistently enforced this explicit statutory prohibition and dismissed claims—just like those here—that would impose requirements that are "different from, or in

addition to" (21 U.S.C. § 360k(a)) those imposed by federal requirements. Indeed, when confronted with materially identical claims to those raised in this case, Judge Kyle of this Court ruled—and the Eighth Circuit recently affirmed—that every single one of those claims was preempted. *See* Part I.

Courts also have uniformly rejected the argument that Section 360k does not preempt claims arising from a device that, like the devices at issue here, has been subjected to a field action the FDA has designated a recall. Given the clear statutory and regulatory distinction between an FDA recall classification on the one hand and a withdrawal of PMA on the other, the uniform rejection of such an argument is unsurprising. Moreover, the recalls at issue in this case involved additional communications to patients and physicians and *not* the removal of the devices from the market. *See* Part II.

Finally, to the extent Kinetic's claims rest on allegations that FDA approval was obtained or retained through improper means (*e.g.*, violations of reporting requirements), as they appear to be, those claims are preempted under 21 U.S.C. § 337(a), which specifies that all actions to enforce the FDCA "shall be by and in the name of the United States," and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). *See* Part III.

STATEMENT OF FACTS

A. The Statutory And Regulatory Framework Governing Class III Medical Devices

Until 1976, the FDA generally lacked authority to regulate medical devices. That year, Congress enacted the MDA, which extended the FDA's regulatory authority to medical devices (PUB. L. No. 94-295, 90 Stat. 539 (1976)) and created a comprehensive "regime of detailed federal oversight" over those devices. *Riegel*, 552 U.S. at 316. In enacting the MDA, Congress struck a careful balance between regulation and innovation. Hence, the MDA "provide[s] for the safety and effectiveness of medical device[s]" (90 Stat. 539), while simultaneously "encourag[ing] the[] research and development" of "sophisticated, critically important" devices. S. Rep. No. 94-33, at 2 (1975); *see* H.R. Rep. No. 94-853, at 12 (1976).

An important purpose of the new federal regime was to ensure that innovations in device technology would not be "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12. Accordingly, Congress incorporated into the MDA an express preemption clause—that is, a "general prohibition on non-Federal regulation" (*id.*) specifying that no state may impose "any requirement" relating to the safety or effectiveness of a medical device or any other matter

regulated by the MDA that "is different from, or in addition to, any requirement applicable … to the device" under federal law (21 U.S.C. § 360k(a)).

In *Riegel*, the Supreme Court confirmed that, by enacting Section 360k(a), Congress expressly preempted any state-law claim that challenges the design, manufacturing process, or labeling of a premarket-approved medical device. 552 U.S. at 327-29. Such claims necessarily would involve a jury second-guessing the FDA's determination that the device was safe and effective and could be marketed and sold as approved. *Id.* at 325.

1. *Premarket Approval And Reporting Requirements*

Under the MDA, different types of devices receive different levels of scrutiny from the FDA. Devices that "support[]" or sustain "human life" or "present[] a potential unreasonable risk of illness or injury" are designated "Class III" devices. 21 U.S.C. § 360c(a)(1)(C)(ii). A Class III device must receive FDA approval before it may be brought to market and "incur[s] the FDA's strictest regulation." *Buckman*, 531 U.S. at 344. The medical devices that are at issue in this litigation, various models of Medtronic ICDs and CRT-Ds (*see* Am. Compl. ¶¶ 19-23) (collectively, the Defibrillator Devices), are all Class III devices that were approved under the FDA's PMA process. *See* page 9 & note 1, *infra*.

The PMA process is the most exacting form of FDA review for medical devices. The FDA "grants premarket approval only if it finds there is a 'reasonable

assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(d)). To obtain FDA approval via the PMA process, a manufacturer "must submit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 109 (2d Cir. 2006) (citing 21 U.S.C. § 360e(c)), *aff'd*, 552 U.S. 312 (2008).

The FDA closely scrutinizes PMA applications, "'weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). If the Agency is not satisfied with the information provided, it can demand more. *See id.* (citing 21 U.S.C. § 360e(c)(1)(G)). As part of the PMA process, the FDA must review the device's proposed labeling to "evaluate[] safety and effectiveness under the conditions of use set forth on the label … and must determine that the proposed labeling is neither false nor misleading." *Id.* (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). If, as a result of this review, the FDA decides that the device's design, manufacturing methods, or labeling should be

revised, it can require such revisions prior to approval. *See id.* at 319 (citing 21 C.F.R. § 814.44(e)).

The FDA's regulatory role does not end with approval of the initial PMA application. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). If a manufacturer wishes to make such changes, it must submit a PMA Supplement and can implement the proposed changes only after FDA approval. *See Riegel*, 451 F.3d at 110 (citing 21 C.F.R. § 814.39(a)); *see also Bryant*, 623 F.3d at 1203. A PMA Supplement is subject to the same rigorous standards of review as an initial PMA application. *Riegel*, 552 U.S. at 319 (citing 21 C.F.R. § 814.39(c)); *see also Bryant*, 623 F.3d at 1203; *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000).

2. *Ongoing Post-Approval Reporting For Approved Devices*

The MDA also imposes post-approval reporting obligations on the manufacturer of an approved device. FDA regulations require a manufacturer "to inform the FDA of new clinical investigations or scientific studies concerning the device … and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would

likely cause or contribute to death or serious injury if it recurred." *Riegel*, 552 U.S. at 319 (citing 21 C.F.R. §§ 803.50(a), 814.84(b)(2)).

3. *Enforcement Of FDA Requirements For Approved Devices*

The FDA has extensive and exclusive enforcement authority with respect to the requirements imposed on Class III devices via the PMA process. Congress has specified that all actions to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Although "citizens may report wrongdoing and petition the agency to take action" (*Buckman*, 531 U.S. at 349 (citing 21 C.F.R. § 10.30)), there is no private right of action under the FDCA. (*id.* at 349 n.4). *See also* Br. for the United States as *Amicus Curiae*, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (per curiam) (No. 06-1498), 2007 WL 4218889, at *4 (Nov. 28, 2007) ("The United States has *exclusive* authority to enforce the [FDCA's] provisions") (emphasis added). Consistent with the agency's exclusive power to enforce the FDCA, the FDA has the authority "to investigate violations of the Act, and to pursue a wide range of sanctions for any fraud it uncovers," (*id.* at *3 (citation omitted)), including "injunctive relief, civil money penalties, seizure of the device, and criminal prosecution." Br. for the United States as *Amicus Curiae*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768), 2000 WL 1364441, at *22 (Sept. 13, 2000) (internal citations omitted).

B. The Medical Devices At Issue In This Case

Kinetic brings claims regarding ten models of ICDs and CRT-Ds. Am. Compl. ¶¶ 19-23. The Defibrillator Devices are battery-operated devices that treat a number of potentially life-threatening ailments such as cardiovascular disease and cardiac arrhythmias. Like any battery-operated device, the Defibrillator Devices have a finite useful life span, usually on the order of roughly four-to-six years, after which they must be replaced. Each of the Defibrillator Devices at issue in this case is a Class III medical device that was approved by the FDA through the PMA process.[1]

Kinetic alleges that in April 2004, two of the Defibrillator Devices, the Micro Jewell® II and GEM® DR ICDs, were subject to "a Class I recall." Am.

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[1] Web addresses for the FDA's PMA approvals of nine of the ten Defibrillator Devices listed in the Amended Complaint are included in the Appendix. The Court may take judicial notice of these approvals because they are public government records that are not subject to reasonable dispute. Fed. R. Evid. 201(b)(2); *see also Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 531 (S.D. Tex. 2009) (taking judicial notice of fact that device was a "Class III device approved through the PMA process" in the course of dismissing complaint on *Riegel* preemption grounds); *Covert v. Stryker Corp*., 2009 WL 2424559, at *1 n.2 (M.D.N.C. Aug. 5, 2009); *Heisner v. Genzyme Corp.*, 2008 WL 2940811, at *1 (N.D. Ill. July 25, 2008).

Kinetic's Amended Complaint references a tenth device, the "Model 7285" (Am. Comp. ¶ 23), which likely refers to the InSync III Protect® Model 7285 CRT-D. That device did not receive premarket approval by the FDA because it was never sold in the United States. *See* Answer ¶ 23; http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=37339 (Model 7285 only distributed "OUS," or Outside the United States). Medtronic accordingly is not seeking judgment on preemption grounds with respect to this device, but respectfully suggests that Kinetic abandon claims about it.

Compl. ¶ 19. Medtronic took the voluntary action of informing patients and physicians of a higher-than-normal charge time in a small subset of these devices, many of which were already close to their normal replacement time. Medtronic recommended that physicians verify the charge time and battery voltage of the affected devices and then schedule a replacement if necessary. The FDA classified Medtronic's voluntary action as a Class I Recall, although no devices were required to be replaced or returned to the manufacturer.[2]

Kinetic further alleges that on February 11, 2005, the remainder of the devices at issue were subject to "a worldwide advisory/recall." Am. Compl. ¶¶ 22-23. The "recall" in question was Medtronic's voluntary letter to physicians informing them about the potential for an increase in the shorting rate during the second half of device life and recommending patient-management options.[3] At the

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[2] *See* FDA, *Medtronic Announces a Nationwide, Voluntarily Recall of Small Subset of Two Implantable Cardioverter-Defibrillator Models* (Apr. 16, 2004), available at http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2004/ucm111586.htm (last visited Dec. 27, 2010) (attached as Exhibit I). This document also is subject to judicial notice. *See* note 1, *supra*.

[3] *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=37336 (FDA summary of action with respect to Model 7277: "Medtronic Sales Representatives contacted affected physicians starting 02/10/05 to deliver an Important Patient Management Information. The letter recommended patient [management] options including quarterly follow-ups, programming Patient Alert to 'On-High', provide magnet to patients to check device status and inform patients that should they [experience] warmth in the area surrounding the ICD to seek prompt care."); http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm? (*cont'd*)

time of this field action, the estimated rate of the shorting mechanism was 1 in 10,000 (0.01%). Medtronic alerted physicians about this potential out of an abundance of caution and because it was possible that the rate of the shorting mechanism could increase over time. To eliminate cost concerns from medical judgment and as a gesture of good will to customers and patients, Medtronic voluntarily offered to provide free replacement devices for those patients whose doctors decided, in their medical judgment, that their patients' devices should be replaced. Because treatment decisions are highly individualized, some devices were replaced; others were not.

Medtronic was never required to replace the Defibrillator Devices or withdraw them from the market. Indeed, the FDA to date—over five years later—has not taken any regulatory enforcement action against Medtronic based on its letter. And, the failure rate of the devices at issue remains within the rate projected in Medtronic's February 2005 letter.

C. Kinetic's Claims Against Medtronic

Kinetic's long-running dispute with Medtronic began in 2005, when it filed a similar action that was consolidated into a multidistrict litigation regarding the Defibrillator Devices. *See In re Medtronic, Inc. Implantable Defibrillators*

start_search=1&event_id=31142 (links to similar explanations for each other device covered by advisory).

Products Liab. Litig., No. 05-MDL-1726 (JMR/AJB) (D. Minn. Dec. 8, 2005) (the MDL). Kinetic was one of six third-party payors that filed complaints against Medtronic and subsequently filed a Master Consolidated Complaint. Individual plaintiffs in the MDL also filed a Master Consolidated Complaint. During the course of the MDL, Medtronic moved for summary judgment on preemption grounds with respect to plaintiffs' claims. Judge Rosenbaum denied that motion. *See* 465 F. Supp. 2d 886 (D. Minn. 2006). But importantly, much has changed since Judge Rosenbaum's order. His order was issued before the Supreme Court's decision in *Riegel*, before Judge Kyle's decision in the *Fidelis Leads* MDL, before the Eighth Circuit's recent decision in *Bryant*, and before the decisions of numerous other courts holding claims materially identical to those advanced by Kinetic in this case preempted. *See* Part I, *infra*.

On April 24, 2008, Judge Rosenbaum entered a stipulated order dismissing Kinetic's previous action without prejudice. On November 5, 2008, Kinetic then filed the present action in state court, which Medtronic timely removed to this Court. Kinetic's original Complaint advanced a laundry list of 14 state-law causes of action, including claims for negligence, negligence per se, strict liability design and manufacturing defect, and strict liability failure to warn. Medtronic moved to

dismiss on standing grounds and for failure to state an actionable claim,[4] which Judge Rosenbaum denied on December 4, 2009. *See* Dkt. # 32.

Kinetic, likely aware that its negligence and strict liability claims were preempted under *Riegel*, abandoned them and on June 22, 2010 filed the operative Amended Complaint. In its Amended Complaint, Kinetic seeks to represent a putative nationwide class of third party payors that have incurred costs related to the Defibrillator Devices (*see* Am. Compl. ¶ 41), and asserts claims for violations of consumer protection statutes (*id*. ¶¶ 48-82), unjust enrichment (*id.* ¶¶ 83-91); breach of express, implied, and assumed warranties (*id.* ¶¶ 92-105); and misrepresentation by omission (*id*. ¶¶ 106-112). Because the Eighth Circuit's recent decision in *Bryant* demonstrates incontrovertibly that these claims are preempted, Medtronic is now moving for judgment on the pleadings.

ARGUMENT

I. Kinetic's Claims Are Preempted By 21 U.S.C. § 360k(a).

Kinetic's claims are preempted by federal law. As the Supreme Court confirmed in *Riegel* and the Eighth Circuit recently stressed in *Bryant*, Congress has precluded plaintiffs from bringing state-law claims challenging the design, manufacturing process, or labeling of a medical device that has been approved by

[4] Medtronic did not include that argument in its motion to dismiss but did preserve its preemption argument in its Answer (at 20-21).

the FDA via the PMA process; such claims necessarily would involve a jury second-guessing the FDA's determination that the device could be marketed as approved.

The MDA preemption clause, the *Riegel* Court clarified, establishes a two-step procedure for determining if state-law claims are preempted. First, a court must determine whether "the Federal Government has established requirements applicable to" the particular medical device. *Riegel*, 552 U.S. at 321. If it has, the court then must determine whether the state-law claims raised by the plaintiff would impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements (*id.* at 322), and that relate to either (i) "safety or effectiveness" or (ii) "any other matter included in a requirement applicable to the device [under the MDA, 21 U.S.C.] § 360k(a)." *Id.* at 321-23 (internal quotation marks omitted). If both these conditions are satisfied, then the claim is preempted.[5]

Claims involving a device that has received premarket approval automatically satisfy the first condition of the test for preemption. As the *Riegel* Court noted, "the FDA requires a device that has received premarket approval to

[5] The express preemption clause in Section 360(k) of the MDA distinguishes this case from the Supreme Court's opinion in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), which addressed preemption in the context of drug labeling, where there is no such provision (*id.* at 1200).

be made with almost no deviations from the specifications in its approval application." 552 U.S. at 323. Thus, the *Riegel* Court held, "[p]remarket approval … imposes [federal] 'requirements'" as that term is used in § 360k(a). *Id.* at 322. All of the devices at issue were approved through the PMA process. *See* page 9 & note 1, *supra*.[6]

Riegel also held that, for purposes of preemption under the MDA, state common-law duties constitute "requirements" (552 U.S. at 324) and, specifically, that "the duties underlying negligence, strict-liability, and implied-warranty claims" are requirements "with respect to devices" (*id.* at 327) (internal quotation marks omitted). The Court explicitly rejected the proposition that, to be preempted, a common-law duty "must apply *only* to the relevant device," or even "only to medical devices and not to all products and all actions in general." *Id*. at 328 (emphasis in original).

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[6] Because the device in *Riegel* was approved through the PMA Supplement process, the Court's holding applies equally to specifications imposed by an original or a supplemental approval. *Riegel*, 552 U.S. at 320; *see also, e.g.*, *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig. (In re Fidelis Leads I)*, 592 F. Supp. 2d 1147, 1153, 1156 n.11 (D. Minn. 2009), *aff'd sub nom. Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010); *In re Medtronic Sprint Fidelis Lead Prods. Liab. State Court Litig.* (*In re Fidelis State Court Litig.*), 2009 WL 3417867, at *10 & n.11 (Minn. D. Ct. Oct. 20, 2009); *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1284 (M.D. Fla. 2009).

Thus, *Riegel* stands unequivocally for the proposition that statutory or common-law causes of action that would impose "different" or "addition[al]" duties relating to any requirement imposed by the premarket approval of a device (21 U.S.C. § 360k(a)) are expressly preempted by the MDA. Since the Supreme Court's decision in *Riegel*, "courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-defect, to negligence *per se*." *In re Fidelis Leads I*, 592 F. Supp. 2d at 1152 (citations omitted), *aff'd sub nom. Bryant*, 623 F.3d 1200. Indeed, "when Sections 337(a) and 360k(a)—as construed in *Buckman* and *Riegel*, respectively—are read together, *nearly all types of claims concerning FDA-approved medical devices*" are preempted." *In re Fidelis Leads I*, 592 F. Supp. 2d at 1161 (emphasis added). In case after case, state and federal courts have applied *Riegel* to reject state-law claims seeking to impose different or additional requirements on PMA-approved medical devices.[7] And these cases make it clear that it does not matter whether the

[7] *See, e.g.*, *Walker v. Medtronic, Inc.*, 2010 WL 4822135 (S.D. W. Va. Nov. 24, 2010) (MDA preempted claims for negligence, strict liability, and breach of warranty); *Cenac v. Hubbell*, 2010 WL 4174573 (E.D. La. Oct. 21, 2010) (MDA preempted claims for negligence, failure to warn, breach of warranty, and products liability); *Bass v. Stryker Corp.*, 2010 WL 3431637 (N.D. Tex. Aug. 31, 2010) (MDA preempted claims for products liability, negligence, breach of implied and express warranties, and statutory fraud); *Franklin v. Medtronic, Inc.*, 2010 WL (*cont'd*)

plaintiff's claims are based on common law or a state-law consumer protection statute; in either instance, any claim that would impose a different or additional

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2543579 (D. Colo. May 12, 2010) (MDA preempted claims for design defect, manufacturing defect, negligence, negligence per se, implied warranty, express warranty, and misrepresentation); *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522 (S.D. Tex. 2009) (MDA preempted claims for design defect, manufacturing defect, failure to warn, and statutory fraud); *McQuiston v. Boston Scientific Corp.*, 2009 WL 4016120 (W.D. La. Nov. 19, 2009) (MDA preempted claims for design defect, manufacturing defect, failure to warn, express warranty, implied warranty, and fraud); *In re Fidelis State Court Litig.*, 2009 WL 3417867 (MDA preempted all claims in consolidated complaint in state MDL); *Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301 (E.D. Pa. 2009), *aff'd*, 2010 WL 2982839 (3d Cir. July 30, 2010) (MDA preempted claims for manufacturing defect and implied warranty); *Covert v. Stryker Corp.*, 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009) (MDA preempted claims for failure to warn, defective design, defective manufacture, negligence, express warranty, and implied warranty); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009) (MDA preempted claims for failure to warn, manufacturing defect, implied warranty, express warranty, misrepresentation, and fraud); *In re Fidelis Leads I*, 592 F. Supp. 2d 1147 (MDA preempted all claims in consolidated complaint in federal MDL); *In re Medtronic Spring Fidelis Lead Prods. Liab. Litig. (In re Fidelis Leads II)*, 2009 WL 1361313, at *2 (denying request to amend complaint in federal MDL because all claims remained preempted); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009) (MDA preempted claims for negligence, defective design, manufacturing defect, failure to warn, express warranty, and implied warranty); *Link v. Zimmer Holdings, Inc.*, 604 F. Supp. 2d 1174 (N.D. Ill. 2008) (MDA preempted claims for strict liability, negligence, and breach of warranty); *Lake v. Kardjian*, 874 N.Y.S.2d 751 (N.Y. Sup. Ct. 2008) (MDA preempted claims for failure to warn, negligence, implied warranty, and express warranty); *Blanco v. Baxter Healthcare Corp.*, 70 Cal. Rptr. 3d 566 (Cal. Ct. App. 2008) (MDA preempted claims for negligence, strict liability, and breach of implied warranty); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298 (D. Colo. 2008) (MDA preempted claims for failure to warn, manufacturing defect, and design defect); *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090 (D. Minn. 2008) (Rosenbaum, J.) (MDA preempted claims for negligence and failure to warn).

requirement on a PMA-approved device is preempted. *See Riegel*, 552 U.S. at 324 ("State *tort* law … disrupts the federal scheme no less than state *regulatory* law to the same effect.") (emphasis added); *see also, e.g.*, *In re Fidelis Leads I*, 592 F. Supp. 2d at 1154 n.9, 1165 (dismissing state consumer protection and other claims); *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127, 137 (Tex. Ct. App. 2005), *cert. denied*, 128 S. Ct. 1441 (2008).

Thus, Section 360k(a) preempts state-law claims that impose a requirement that differs from or adds to federal requirements for a PMA-approved medical device. It is irrelevant for purposes of the preemption analysis whether such claims are brought by individual patients or, as in this case, a purported third party payor. Indeed, Judge Kyle held in the *Fidelis Leads* MDL that his preemption analysis applied with equal force to the third party payor plaintiffs in that case, "requir[ing] the dismissal of the claims in the [third party payors'] Master Consolidated Complaint." *In re Fidelis Leads I*, 592 F. Supp. 2d at 1165; *see also id.* ("In the absence of any viable claim by the individual Plaintiffs, [third party payors'] claims also fail.").

As shown below, each of the claims raised in this case is preempted under this precedent.

A. Consumer Protection Act Claims

Kinetic's first four causes of action assert that Medtronic's alleged misrepresentations about the "soundness and mechanical reliability of the Devices" and alleged concealment of "design defects" in the Defibrillator Devices violated Minnesota's False Statements in Advertising Statute, Deceptive Trade Practice Act, Prevention of Consumer Fraud Act, and the state consumer protection acts for all fifty states plus the District of Columbia. Am. Compl. ¶¶ 44-82. At their core, these claims are based upon the simple allegation that the Defibrillator Devices were defective. All of these statutory consumer protection claims are thus preempted because they would require a jury to determine that FDA-approved statements about the Defibrillator Devices were inadequate or that the devices were "defective." *Id.* ¶ 56. Such claims are preempted for the same reason that the underlying design defect and failure to warn claims are preempted; the fact that these claims invoke a state regulatory statute rather than common law is irrelevant. *See Riegel*, 552 U.S. at 324; *In re Fidelis Leads I*, 592 F. Supp. 2d at 1154 n.9, 1165; *Baker*, 178 S.W.3d at 137.

In particular, plaintiffs' statutory claims that are dependent, either explicitly or implicitly, on its theory that the Defibrillator Devices had a "defective design" or were not "safe and medically effective" as designed (Am. Compl. ¶¶ 33, 85; *see id.* ¶¶ 49, 55-63, 66, 72, 94, 100, 107-109) are preempted. To prevail on any of these claims, Kinetic necessarily would have to prove that each of the Defibrillator

Devices should have been designed differently from the manner approved in its PMA. Any such claim is straightforwardly preempted under *Riegel*. *See* 552 U.S. at 320; *Bryant*, 623 F.3d at 1206; *see generally* cases cited at note 7, *supra*.

Kinetic's statutory claims that are dependent on its theory that Medtronic "failed to adequately warn consumers and the medical community of the safety risks associated with the [Defibrillator Devices]" (Am. Compl. ¶ 51; *see id.* ¶¶ 56, 66, 74, 86, 107-110), are also preempted by Section 360k(a).[8] These claims are preempted because they depend on a finding that the Defibrillator Devices should have carried labels different from the ones that were required by the FDA, or that Medtronic should have supplemented the FDA-approved product labels with additional warnings. As Judge Kyle explained when confronted with nearly identical claims, "under [this] theory of liability, Medtronic would have been required to provide warnings above and beyond those on the … product label—a label that was specifically approved by the FDA as part of the PMA process"—which means that these claims would "impose requirements 'different from, or in addition to' those approved by the FDA." *In re Fidelis Leads I*, 592 F. Supp. 2d at 1159; *see also Bryant*, 623 F.3d at 1205 (allegation that "by reason of state law,

[8] To the extent Kinetic alleges that Medtronic failed to warn the *FDA* of purported defects in the Defibrillator Devices, Kinetic's claims are also preempted under 21 U.S.C. § 337(a) and *Buckman*. *See* Part III, *infra*.

Medtronic was required to give additional warnings" imposes "precisely the type of state requirement that is 'different from or in addition to' the federal requirement and therefore preempted"); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489–90 (7th Cir. 2005); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796–98 (8th Cir. 2001) (en banc); *King v. Collagen Corp.*, 983 F.2d 1130, 1136 (1st Cir. 1993); *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1021 (E.D. Mich. 1993); *Talbott v. C.R. Bard, Inc.*, 865 F. Supp. 37, 51–52 (D. Mass. 1994), *aff'd*, 63 F.3d 25 (1st Cir. 1995); *Blanco*, 70 Cal. Rptr. 3d at 579.

B. Unjust Enrichment

Kinetic's unjust enrichment claim is entirely dependent on its core underlying allegation that the Defibrillator Devices were not "safe and medically effective" as approved by the FDA and is preempted as well. Am. Compl. ¶¶ 85, 88. As Judge Kyle explained when confronting a similar claim, Kinetic's unjust enrichment claim is "derivative of [its] other claims and hence cannot stand." *In re Fidelis Leads I*, 592 F. Supp. 2d. at 1165. Because Kinetic's underlying claims are preempted, so too is this derivative claim. *See also Riegel*, 552 U.S. at 321 (affirming district court's conclusion that "the MDA preempted [the plaintiff's] claim for loss of consortium to the extent it was derivative of the pre-empted claims").

C. Express Warranty

Kinetic alleges that Medtronic "expressly warranted … that the [Defibrillator Devices] were safe, effective, fit, and proper for [their] intended use." Am. Compl. ¶ 93. Although Kinetic does not specify the statements that allegedly gave rise to these express warranties, Kinetic's claim that Medtronic breached any such warranty necessarily would depend on a finding that the Defibrillator Devices were "not safe" or "unfit for the uses for which they were intended" (*id.* ¶ 94)—a finding that inevitably would contradict the FDA's conclusive determination that the devices were safe and effective as labeled. As Judge Kyle explained, express warranty claims "based on an allegation that [devices] were represented as safe … but were not" are preempted because they would require a jury "to conclude that the … [devices] were unsafe" whereas "the FDA determined that the [devices] were safe and effective when granting PMA." *In re Fidelis Leads I*, 592 F. Supp. 2d at 1164; *see also, e.g.*, *Bryant*, 623 F.3d at 1207-08; *Gomez v. St. Jude Med. Daig Div., Inc.*, 442 F.3d 919, 932 (5th Cir. 2006); *Horowitz*, 613 F. Supp. 2d at 282; *Parker*, 584 F. Supp. 2d at 1303.[9]

D. Implied Warranty

[9] Because the express warranties alleged by Kinetic relate to the safety and effectiveness of the devices, Kinetic's express warranty claim is distinct from the express-warranty claims dealing with collateral issues that courts have found are not preempted. *Compare Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997).

Kinetic's claim that Medtronic violated an implied warranty that the Defibrillator Devices "were of merchantable quality and safe and fit for the use for which they were intended" (Am. Compl. ¶ 98) necessarily depends on a finding that the Defibrillator Devices were unsafe or ineffective and thus should have been designed, manufactured, labeled or sold differently from the manner approved by the PMA. *Riegel* is, again, on-point authority that such claims are preempted. *See* 552 U.S. at 320 ("the MDA pre-empt[s] … claims of … breach of implied warranty"); *In re Fidelis Leads I*, 592 F. Supp. 2d at 1163–64; *see generally* cases cited in note 7, *supra*.

E. Breach Of Assumed Contractual Warranty Obligations

Kinetic's breach of assumed warranty obligations claim is similarly entirely dependant on establishing that Medtronic breached the "express and implied warranties" provided "directly to consumers." Am. Compl. ¶ 103. For the reasons discussed above as to Kinetic's express and implied warranty claims, this claim too is preempted under *Riegel*.

F. Misrepresentation By Omission

To prove that Medtronic's alleged "misrepresentations and omissions" regarding the "mechanical soundness and reliability" of the Defibrillator Devices were false or misleading (Am. Compl. ¶¶ 107, 110), Kinetic, again, necessarily must "challeng[e] the safety and effectiveness of a medical device given premarket

approval by the [FDA]." *Riegel*, 552 U.S. at 315. That type of claim is expressly preempted. *Id.*

Moreover, as noted above (at pages 18-20), courts consistently have found that claims based on alleged misrepresentations about a PMA-approved device are preempted because they would require warnings or disclosures that are different from or in addition to those required by the FDA. *See, e.g.*, *Bryant*, 623 F.3d at 1205; *In re Fidelis Leads I*, 592 F. Supp. 2d at 1159-61; *King*, 983 F.2d at 1136; *Kemp*, 835 F. Supp. at 1021 ("claims of fraud and fraudulent concealment" preempted); *McMullen*, 421 F.3d at 489-90.

II. The Recall Does Not Revive Kinetic's Preempted Claims.

Based on Kinetic's Amended Complaint, we anticipate that Kinetic will argue that the "recalls" of the Defibrillator Devices negate Medtronic's preemption defense. But every court to consider the issue has held that the recall of a device neither invalidates PMA nor negates the federal requirements applicable to a device with PMA. *See, e.g.*, *Bryant*, 623 F.3d at 1205 n.4; *In re Fidelis Leads I*, 592 F. Supp. at 1155-56; *Horowitz*, 613 F. Supp. 2d at 282; *Bausch v. Stryker Corp.*, 2008 WL 5157940, at *3 (N.D. Ill. Dec. 9, 2008), *rev'd on other grounds*,

__ F.3d __, 2010 WL 5186062 (7th Cir. Dec. 23, 2010)[10]; *Kemp*, 835 F. Supp. at 1023; *In re Fidelis State Court Litig.*, 2009 WL 3417867, at 11; *Mitaro v. Medtronic, Inc.*, 886 N.Y.S.2d 71 (table), 2009 WL 1272398, at *6 (N.Y. Sup. Ct. 2009); *Blanco*, 70 Cal. Rptr. 3d at 579-80; *Baker*, 178 S.W.3d at 132.

The fact that courts unanimously have found that a recall does not affect preemption is unsurprising because the regulatory structure draws a clear distinction between recall and the withdrawal of PMA. Recalls of Class III medical devices are governed either by 21 C.F.R. §§ 7.40-7.59 (for voluntary manufacturer actions that the FDA classifies as recalls, such as here), or by 21 U.S.C. § 360h(e) and 21 C.F.R. §§ 810.10-810.18 (for mandatory recalls). Nothing in these regulations even remotely suggests that a recall results in the withdrawal of a device's PMA. To the contrary, an entirely separate statutory and regulatory process governs withdrawal of PMA. *See* 21 U.S.C. § 360e(e); 21 C.F.R. § 814.46. Indeed, the standards for withdrawal of PMA are distinct from those governing recalls. *Compare* 21 U.S.C. § 360e(e)(1) *with* 21 C.F.R. §§ 7.40(a), 7.41(a),

[10] While the Seventh Circuit recently reversed the district court's decision in *Bausch*, *see* 2010 WL 5186062, the Seventh Circuit did not question the district court's holding that the device at issue in that case was PMA-approved despite a later recall. Although the Seventh Circuit questioned certain aspects of the Eighth Circuit's decision in *Bryant*, the disagreement between the Seventh and Eight Circuits – over whether certain types of claims based on "violations of federal law in manufacturing [a] device" can survive a motion to dismiss (2010 WL 5186062, at *5) –is immaterial here, as Kinetic has not brought such claims.

7.46(a). And the revocation of PMA requires explicit FDA action pursuant to a specific statutory and regulatory procedure. *See, e.g.*, 21 U.S.C. §§ 360e(e)(2), 360e(g)(1)(A); 21 C.F.R. §§ 10.45, 16.62, 16.80, 16.95(b)(2), 16.120, 814.46(c).

Indeed, this case provides a perfect demonstration why a recall classification does not change the preemption analysis. Although Medtronic made the decision to voluntarily recall a subset of Micro Jewel® II and GEM® DR ICDs, many of which were already close to their normal replacement time, the FDA did not require Medtronic to replace the devices or withdraw them from the market. Similarly, although the FDA classified Medtronic's communications with physicians and patients regarding the Marquis and Maximo ICDs as a recall, many of the devices have legally remained on the market and the agency has not initiated proceedings to withdraw PMA of any of the devices. Kinetic does not allege otherwise. Accordingly, all of the PMAs remain valid and 21 U.S.C. § 360k(a) still preempts any state-law claim that would impose additional or different requirements. *See Bryant*, 623 F.3d at 1205 n.4; *In re Fidelis Leads I*, 592 F. Supp. 2d at 1156; *Talbott*, 63 F.3d at 28.

III. Allegations That Medtronic Obtained Or Maintained PMA By Violating FDA Reporting Requirements Are Preempted Under 21 U.S.C. § 337(a) And *Buckman*.

Kinetic's Amended Complaint contains a number of conclusory allegations that Medtronic concealed information regarding the Defibrillator Devices from the

FDA. *See, e.g.*, Am. Compl. ¶ 29 (Medtronic "did not immediately advise the FDA" of alleged "battery failure problems"). These allegations—for which there is no factual basis whatsoever—do not save Kinetic's claims from preemption. Specifically, any allegation that depends on a finding that Medtronic obtained or maintained premarket approval for the Defibrillator Devices through conduct that violated FDA reporting requirements is preempted under 21 U.S.C. § 337(a) and *Buckman*. *See In re Fidelis Leads I*, 592 F. Supp. 2d at 1159–61.

In *Buckman*, the Supreme Court held that the MDA impliedly preempts state-law claims for personal injuries that the plaintiff contends were caused by the manufacturer's fraud in connection with approval of a device under Section 510(k) (an approval process that is much less rigorous than the PMA process). 531 U.S. at 343, 348. Noting that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used … to achieve a somewhat delicate balance of statutory objectives" under Section 510(k) (*id.* at 348), the Court held that fraud-on-the-FDA claims—*i.e.*, claims that a manufacturer violated FDA disclosure regulations—"inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives" (*id.* at 350) and thus are preempted under the conflict preemption principles that arise out of the Supremacy Clause of the United States Constitution.

The Court's analysis in *Buckman* applies with even greater force in the PMA context. *See In re Fidelis Leads I*, 592 F. Supp. 2d at 1159–61; *Talbott*, 63 F.3d at 28 ("Congress did not intend to provide for an exception to the MDA's preemption clause where a manufacturer fails to comply with the provisions of the MDA by fraudulently obtaining approval of its device from the FDA."); *Link*, 604 F. Supp. 2d at 1179 ("allegations that [the manufacturer of a device with PMA] committed a fraud upon the FDA are … preempted [under *Buckman*]"). The PMA process seeks to achieve a balance of statutory objectives that is even more delicate than that of Section 510(k). *See Riegel*, 552 U.S. at 317-18. Allowing varying state-law standards to govern applicants' conduct could easily upset that balance. Moreover, were applicants "to submit a deluge of information" out of "fear that their disclosures to the FDA, although deemed appropriate by the Administration, w[ould] later be judged insufficient in state court," the FDA's already complicated task would be rendered all the more difficult. *Buckman*, 531 U.S. at 351.

Furthermore, permitting private litigants to bring a cause of action that would void the preemptive effect of a device's PMA simply because they allege that material information (as they define it) was withheld from the FDA would be tantamount to allowing a private action seeking to rescind a PMA. Such an action is expressly prohibited under 21 U.S.C. § 337(a), and would conflict with Congress's intent that "the MDA be enforced exclusively by the Federal

Government." *Buckman*, 531 U.S. at 352; *see also In re Fidelis Leads I*, 592 F. Supp. 2d at 1161.[11]

In any event, as the expert agency charged with balancing all considerations of safety and efficacy, the FDA—not a jury—should determine whether fraud has occurred, whether a manufacturer has complied with FDA disclosure requirements, and, if not, what response is appropriate given all of the competing interests at stake. *Riegel*, 552 U.S. at 325 ("A jury … sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."); *see also Talbott*, 63 F.3d at 29 ("Allowing an exception for noncompliance would disturb the balance Congress struck between the competing goals of protecting individuals from unreasonably dangerous medical devices and spurring innovation by ensuring that device manufacturers are subject to uniform, nationwide standards."). Allowing juries to

[11] Indeed, even a finding of fraud on the FDA would not automatically invalidate PMA. *See* 21 C.F.R. § 814.46; *see also Talbott*, 63 F.3d at 28–30 (preemption applies even when the FDA has determined that the manufacturer submitted fraudulent data during the PMA process). Rather, federal law commits the decision whether to revoke PMA in the face of fraud to the FDA's "discretion." 56 Fed. Reg. 46,191, 46,193 (Sept. 10, 1991); *see also id.* at 46,200 (upon a finding of fraud, "the agency intends ordinarily [*i.e.*, not automatically] to exercise its authority, under applicable statutes and regulations … to proceed to withdraw approval"). Accordingly, no showing of fraud under state law—much less a mere allegation thereof—could undo the preemptive effect of a valid PMA unless and until the FDA takes discretionary action exercising its statutory authority to withdraw approval. No such action has been taken with respect to the Defibrillator Devices.

(i) interpret FDA reporting regulations (in ways that might vary from jury to jury and substantially depart from the FDA's interpretation); (ii) decide whether a manufacturer had complied with those regulations (according to the jury's non-expert understanding of the medical and scientific processes, norms, and information at issue); and (iii) decide what response is appropriate for a violation (perhaps turning what the FDA would see as a technical violation into a multi-million dollar judgment that could force a needed medical device from the market), would impermissibly usurp the Agency's powers and interfere with the proper functioning of the regulatory scheme created by Congress.[12]

CONCLUSION

For the foregoing reasons, judgment should be entered for Medtronic on all claims.

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[12] This result does not leave a plaintiff who suspects fraud without recourse. As the Supreme Court has emphasized, "citizens may report wrongdoing and petition the agency to take action." *Buckman*, 531 U.S. at 349 (citing 21 C.F.R. § 10.30). If the FDA, in its expert opinion, agrees with the complaint, it "may respond to fraud by seeking injunctive relief" or "civil penalties," "seizing the device," and/or "pursuing criminal prosecutions." *Id.* "The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud …." *Id.*

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